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Section 1 - Identification

- (a) **Product Identifier:** Vecuronium Bromide for Injection (10 mg and 20 mg/vial)
- (b) **Product Code:** 25021-657, 25021-658
- Common/Trade Name:** Norcuron[®]
- Chemical Name:** Vecuronium Bromide
- Chemical Family:** Amino-Steroid
- (c) **Product Use:** Neuromuscular blocking agent
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** US OSHA: Target Organ Toxin, Possible Irritant

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Signal Word:</u>	- Not available
<u>Hazard Statements:</u>	
- Non-hazardous in accordance with international standards for workplace safety	
<u>GHS Precautionary Statements</u>	
<u>Prevention</u>	
- P260: Do not breathe dust/fume/vapors/spray	
<u>Response</u>	
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention	
- Get medical attention if you feel unwell	

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(d) **Unknown Acute Toxicity:** N/A


Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
[(2 <i>S</i> ,3 <i>S</i> ,5 <i>S</i> ,8 <i>R</i> ,9 <i>S</i> ,10 <i>S</i> ,13 <i>S</i> ,14 <i>S</i> ,16 <i>S</i> ,17 <i>S</i>)-17-Acetyloxy-10,13-dimethyl-16-(1-methyl-3,4,5,6-tetrahydro-2 <i>H</i> -pyridin-1-yl)-2-(1-piperidyl)-2,3,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydro-1 <i>H</i> -cyclopenta[<i>a</i>]phenanthren-3-yl] acetate bromide	Vecuronium Bromide, USP	7% (w/w)	50700-72-6	N/A
Sodium hydrogen phosphate	Sodium Phosphate, Dibasic Anhydrous	11% (w/w)	7558-79-4	N/A
2-hydroxypropane-1,2,3-tricarboxylic acid	Citric Acid Anhydrous	14% (w/w)	77-92-9	N/A
(2 <i>R</i> ,3 <i>R</i> ,4 <i>R</i> ,5 <i>R</i>)-Hexan-1,2,3,4,5,6-hexol	Mannitol, NF	67% (w/w)	69-65-8	N/A
Sodium Hydroxide	Sodium Hydroxide, NF	Trace	1310-73-2	N/A
trihydroxidooxidophosphorus phosphoric acid	Phosphoric Acid, NF	Trace	7664-38-2	N/A

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes.

Skin Exposure: Wash skin with cool, soapy water for 15 minutes; remove contaminated clothing.

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Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information

Injection: See patient package insert in shipping carton for complete information.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.


Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use water or a type ABC multi-purpose extinguisher.
- (b) **Hazardous Combustion Products:** None
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

Section 6 - Accidental Release Measures

Spill: Lightly wet Vecuronium Bromide powder and absorb with a damp absorbent cloth. Dispose according to local, state and federal regulations. Wear latex or nitrile gloves.

Release to Air: If dust enters air, reduce exposures by ventilating the area; clean up the spill immediately.

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Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.


Expulsion of air from drug-filled syringes.

Storage Conditions: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Store at temperatures between 15-30°C (59-86°F).

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Vecuronium Bromide	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Citric Acid Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Sodium Phosphate Dibasic Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

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(b) Engineering Controls


Ventilation: Use with adequate ventilation such as a Class II Type A Biological Safety Cabinet.

(c) Individual Protection Measures

Respiratory Protection:	Under normal use, respirators are not needed.
Eye Protection:	Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.
Skin Protection:	Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.
Other Protective Equipment:	None
Additional Exposure Precautions:	No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Section 9 - Physical and Chemical Properties

(a) Appearance	Solid white powder
(b) Odor	No Odor
(c) Odor Threshold	None
(d) pH	3.5 – 4.5
(e) Melting Point:	227-229°C
(f) Initial Boiling Point:	Not available
(g) Flash Point	Not established
(h) Evaporation Rate:	Not applicable
(i) Flammability	Not established
(j) Upper Lower Flammability or Explosion Limits	Not established
(k) Vapor Pressure:	Not applicable

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(l)	Vapor Density:	Not applicable
(m)	Relative Density	Not applicable
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not established
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Reactive
(b)	Chemical Stability	Stable under normal storage handling conditions.
(c)	Possibility of Hazardous Reactions	Will not occur.
(d)	Conditions to Avoid	None
(e)	Incompatible Materials	This product is generally compatible with other common materials in a medical facility. Keep away from strong acids, strong bases and strong oxidizers.
(f)	Hazardous Decomposition Products	Heat may cause product to decompose, destroying the product or producing toxic fumes.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin, ingested and inhalation
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Vecuronium is a drug product that is a smooth muscle relaxer used in association with general anesthesia when intubating patients. It affects the central nervous system and muscular systems.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Excessive exposure may induce paralysis with risks for respiratory failure and vomiting. It may also cause irritation of eyes, skin and respiratory tract. May cause dizziness, headache, weakness and loss of coordination.

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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Vecuronium Bromide	LD ₅₀	Oral	Rat	455 mg/kg
Vecuronium Bromide	LD ₅₀	Oral	Mouse	41 mg/kg
Vecuronium Bromide	LD ₅₀	Interperatoneal	Rat	2630 mcg/kg
Vecuronium Bromide	LD ₅₀	Intraperatoneal	Mouse	142 mcg/kg
Vecuronium Bromide	TD _{LO}	Oral	Woman	130 mcg/kg
Vecuronium Bromide	LD ₅₀	Subcutaneous	Rat	1730 mcg/kg
Vecuronium Bromide	LD ₅₀	Intravenous	Rat	200 mcg/kg
Vecuronium Bromide	LD ₅₀	Intravenous	Mouse	50 mcg/kg
Citric Acid	LD ₅₀	Oral	Rat	11700 mg/kg
Citric Acid	LD ₅₀	Oral	Mouse	5040 mg/kg
Citric Acid	LD ₅₀	Intravenous	Mouse	43 mg/kg
Citric Acid	LD ₅₀	Intravenous	Rabbit	330 mg/kg
Mannitol	LD ₅₀	Oral	Mouse	22,000 mg/kg
Mannitol	LD ₅₀	Intravenous	Mouse	7470 mg/kg
Mannitol	LD ₅₀	Oral	Rat	13,500 mg/kg
Mannitol	LD ₅₀	Intravenous	Rat	9690 mg/kg
Dibasic Sodium Phosphate	LD ₅₀	Oral	Rat	17,000 mg/kg


Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

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Section 12 - Ecological Information

(a)	Ecotoxicity	Not a DOT Hazardous Material or Marine Pollutant
(b)	Persistence and degradability	Not a DOT Hazardous Material or Marine Pollutant
(c)	Bioaccumulative potential	Not a DOT Hazardous Material or Marine Pollutant
(d)	Mobility in soil	Not a DOT Hazardous Material or Marine Pollutant
(e)	Other Adverse Effects	Not a DOT Hazardous Material or Marine Pollutant

Section 13 - Disposal Considerations

Incineration in an approved/permitted incinerator is recommended. Refer to local, state, and federal disposal guidelines.


Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not regulated

ICAO/IATA: Not regulated

IMDG: Not regulated

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Citric Acid, Mannitol, and Dibasic Sodium Phosphate are listed

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.


1901 N. Roselle Rd, Suite 700

Schaumburg, IL 60195

847-908-1600

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency

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EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System